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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,361	09/11/2003	Manfred Bohn	02481.1580-02000	3001

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EXAMINER	
YU, GINA C	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
06/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/659,361	BOHN ET AL.	
	Examiner	Art Unit	
	Gina C. Yu	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,28-47 and 49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 28-47, and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of amendment filed on April 2, 2007. Claims 1, 28-47, and 49 are pending. Claim rejection made under 35 U.S.C. § 112, first paragraph, as indicated in the previous Office action dated October 10, 2006, is withdrawn, due to the clam cancellation made by applicants. Obviousness rejections made under 35 U.S.C. § 103(a), as indicated in the same Office action, are modified to address the claim amendment, but otherwise maintained in substance.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 28-36, 38, 40-45, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein (US 4250164) in view of Rossomando (US 4179304) and Fredriksson (US 3966924).

Bernstein teaches a method of treating nail psoriasis by applying onto the infected nail a lacquer composition comprising a glucocorticoid as a sole active ingredient. The reference teaches that fluocinolene acetonide, fluorandrenolide, triamcinolene acetonide, and betamethasone valerate have been used in topical formulation to treat psoriasis. See col. 1, line 19 – col. 2, line 5. Example 1 shows a nail polish composition comprising Valisone lotion (betamethasone valerate in isopropyl alcohol and carboxy vinyl polymer) and Revlon® clear nail polish. The method of using the composition is taught in Examples 2-4. See instant claim 49.

While Bernstein does not explicitly disclose the constituents of the Revlon nail polish, it is viewed that the Revlon product used in the Bernstein example contains the nail polish ingredients of the present invention of instant claims 1, 33-36, 38, and 40-45.

Rossomando teaches in col. 1, line 67 – col. 2, line 6, "a typical nail polish formulation as sold by Revlon, Inc., of New York has the following ingredients: butyl acetate, toluene, nitrocellulose, ethyl acetate, isopropyl alcohol, toluenesulfonamide/ formaldehyde resin, dibutyl phthalate, camphor . . . and malic acid." See instant claims 33-35 and 40-45. Rossomando also teaches that copolymers of alkyl acrylates and methacrylates are well known film-forming polymers for nail polish formulations. See col. 3, lines 17-20; instant claims 36 and 38.

Bernstein fails to teach clobetasol propionate, the glucocorticoid of instant claim 1, and the amount of the active ingredient as recited by applicants in claims 28 and 29.

Fredriksson teaches that clobetasol propionate and betamethasone valerate are art-recognized equivalents for treating psoriasis. The prior art invention is directed to a synergistic formulation comprising 5-fluorouacil and a halogenated corticosteroid composition, which include flurandrenolone acetonide, betamethasone valerate, fluocinolone acetonide, triamcinolone acetonide, and clobetasol propionate. See col. 1, line 57 – col. 2, line 16. See instant claims 1 and 30. The reference teaches using 0.01-5 % of the corticosteroid in a suitable vehicle. See instant claims 28, 29 and 32.

While the claim limitation of claim 31 requires at least 8 % by weight of glucocorticoid, examiner notes that differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general

conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is viewed that one or ordinary skill in the art would have modified the amount of the glucocorticoid with the motivation to make a strengthened anti-psoriasis formulation.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the Bernstein composition by substituting the glucocorticoids therein with clobetasol propionate as motivated by Fredriksson because the latter teaches that clobetasol propionate and betamethasone valerate are art-recognized equivalents. Given the teaching of a nail polish comprising a glucocorticoid as a sole active ingredient, the skilled artisan would have had a reasonable expectation of successfully producing an anti-psoriatic nail polish that comprises clobetasol propionate as the sole active ingredient.

Claim 37, 39, 46, 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein, Rossomando and Fredriksson as applied to claims 1, 28-36, 38, 40-45, and 49 as above, and further in view of Bohn (US 5264206).

The combined references fail to teach the film-forming agent of instant claims 37-39 and the additives of instant claims 46 and 47.

Bohn teaches nail lacquer compositions to treat mycoses of nails. The reference teaches the film-forming agents of instant claims 36 and 38, which include polyvinyl acetate, copolymers of vinyl acetate, acrylic acid or crotonic acid or monoalkyl maleates. See col. 2, line 58 – col. 4, line 28. The copolymer of methyl vinyl ether and mono-n-butyl maleate is especially preferred. See instant claim 37. The copolymer of

instant claim 39 is taught in Example 2. The reference teaches that the film-formers can be mixed with cellulose nitrate (which is used in the Revlon nail polish composition). See col. 4, lines18-23. The reference also teaches the additives that are commonly used in nail lacquer art, which include 2-hydroxy-4-methoxybenzophenone, ammonium sulfite, esters and salts of thioglycolic acid, urea, allantoin, enzymes, and salicylic acid. See col. 4, line 50 – col. 5, line 24. See instant claims 46 and 47.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Bernstein by adopting the nail lacquer formulation of Bohn, as motivated by the latter reference, because both references are directed to nail lacquer compositions for treating antifungal infections. The skilled artisan would have had a reasonable expectation of successfully producing an anti-psoriasis nail lacquer composition with similar occlusive effects.

Response to Arguments

Applicant's arguments filed on April 2, 2007 have been fully considered but they are unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The present rejection is based on what the combined teaching would have taught a skilled artisan at the time of the invention. What each reference fails to teach does not specifically address the rejection.

Applicants argue that making clobetasol propionate nail polish as suggested by the prior art would somehow produce an unstable composition. There is no specific evidence to support the argument.

Applicants also argue that the purpose of the US 924 patent, Frederickson, is to use a combination of 5-fluorouracil and corticosteroid in a specified amount, and is not related to the present invention. As indicated in the rejection, the reference cited to show that betamethasone valerate of the Bernstein prior art and clobetasol propionate of the present invention are art recognized functional equivalent, which is the main objective evidence that a skilled artisan would have been motivated to use one type of corticosteroid in exchange of another. Applicants' arguments do not address why, in view of the teaching of this evidence, a skilled artisan would have believed that simply modifying the Bernstein prior art with another type of corticosteroid and use different nail lacquer additives would be nonobvious to the skilled artisan.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605. The examiner can normally be reached on Monday through Friday, from 8:00AM until 5:30 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gina C. Yu
Patent Examiner

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER